



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Alice E. Till, Ph.D.
President
Generic Pharmaceutical Industry Association
1620 I Street, N.W., Suite 800
Washington, D.C. 20006

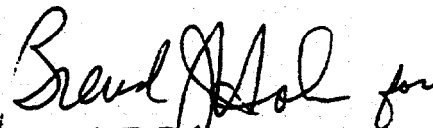
Christina Sizemore
President
National Pharmaceutical Alliance
421 King Street, Suite 222
Alexandria, Virginia 22314

Re: Docket No. 98P-0869/CP1 and PSA1

Dear Dr. Till and Ms. Siore:

This **letter** responds to your citizen petition and petition **for stay of action** dated **October 5, 1998** in which you request that the Food and Drug **Administration (FDA)** **take certain actions regarding pediatric** exclusivity. Your petitions are denied. **The issues you** raised in your petitions were resolved by the lawsuit **National Pharmaceutical Alliance v. Henney** Civ. Action No. **99-0394 (D.D.C. 1999)**. **In** that lawsuit, FDA **explained** and defend& its interpretation of the pediatric exclusivity provisions. We **enclose a copy of the Agency's** brief and the court's decision on a Motion for Preliminary **Injunction**, in which **the** court supports the Agency's interpretation of the **pediatric** exclusivity provisions.¹

Sincerely yours,


Dennis E. Baker
Associate Commissioner
for Regulatory Affairs

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Enclosures

¹ This case has since been dismissed by agreement of the parties.

98P-0869

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